DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 23, 2015

Eppendorf AG
% JoAnne Bronikowski
Regulatory Services Senior Project Manager
Aptiv Solutions
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K142207
Trade/Device Name: TransferMan® 4m Micromanipulator
CellTram® Air Microinjector
CellTram® Oil Microinjector
CellTram® vario Microinjector
Regulation Number: 21 CFR 884.6150
Regulation Name: Assisted reproduction micromanipulators and microinjectors
Regulatory Class: Class II
Product Code: MQJ
Dated: December 17, 2014
Received: January 23, 2015

Dear JoAnne Bronikowski,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142207

Device Name
TransferMan® 4m Micromanipulator; CellTram® Air Microinjector; CellTram® Oil Microinjector; CellTram® vario Microinjector

Indications for Use *(Describe)*

TransferMan® 4m Micromanipulator Indications for Use:
The TransferMan® 4m Micromanipulator is intended for use in assisted reproduction procedures requiring coarse and fine positioning of a microtool under the microscope.

CellTram® Air Microinjector / CellTram® Oil Microinjector / CellTram® vario Microinjector Indications for Use:
The CellTram® Microinjectors are intended for use in Intra-Cytoplasmic Spermatozoa Injection (ICSI) procedures to aspirate and inject sperm into oocytes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary for the Eppendorf AG
TransferMan® 4m Micromanipulator and CellTram® Microinjectors
(per 21CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

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Date Prepared: July 28, 2014

2. DEVICE NAME

Trade Name:	TransferMan® 4m Micromanipulator CellTram® Air Microinjector CellTram® Oil Microinjector CellTram® vario Microinjector
Common Name:	Micromanipulator and microinjectors
Device Name:	Assisted reproduction micromanipulators and microinjectors
Classification Panel:	Obstetrics/Gynecology Devices
Classification Number:	884.6150
Product Code:	MQJ

3. PREDICATE DEVICES

The proposed TransferMan® 4m Micromanipulator and CellTram® Microinjectors are substantially equivalent to other legally marketed assisted reproduction micromanipulators and microinjectors including the following:

- IM-11 Pneumatic Microinjector (Narishige Co., Ltd., K113712)
- NAI-5 Micromanipulator Set (Narishige Co., Ltd., K120877)*

* *Eppendorf is claiming substantial equivalence of the proposed TransferMan® 4m Micromanipulator only to the Micromanipulator, not to the NAI-5 Micromanipulator Set as a whole.*

A comparison of the intended use and features of the proposed TransferMan® 4m Micromanipulator and CellTram® Microinjectors and the predicate devices described in K113712 and K120877 is provided in Table 5-1.

4. DEVICE DESCRIPTION

The TransferMan® 4m Micromanipulator is a motorized micromanipulator consisting of a Motor module unit and a Control board that allows the user to precisely control the movement of tools (i.e., microcapillaries) used for Intra-Cytoplasmic Spermatozoa Injection (ICSI) and other In Vitro Fertilization (IVF) procedures. The tool is mounted in a Universal Capillary Holder on the TransferMan® 4m Micromanipulator's Motor module unit that is, itself, mounted to an inverted microscope. The user controls the movements of the tool using a joystick on the Control board. The Motor module unit shifts the position of the tool in response to the joystick motions.

The CellTram® Microinjectors are manual piston pumps for holding and transfer of suspension cells (e.g., oocytes and sperms for use in ICSI procedures), used in manual microinjection procedures. Using a movable piston in a cylinder system, the CellTram® Microinjectors generate differences in pressure that are transferred directly to a microcapillary via a connected pressure tube. Depending on the piston movement, material can be aspirated or dispensed. Three versions of the CellTram® Microinjectors will be marketed for use in ICSI procedures, the CellTram® Air, the CellTram® Oil, and the CellTram® vario. The three versions differ in the medium used for pressure transmission (air versus oil).

5. INDICATIONS FOR USE

The TransferMan® 4m Micromanipulator is intended for use in assisted reproduction procedures requiring coarse and fine positioning of a microtool under the microscope.

The CellTram® Microinjectors are intended for use in Intra-Cytoplasmic Spermatozoa Injection (ICSI) procedures to aspirate and inject sperm into oocytes.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

Both the proposed TransferMan® 4m Micromanipulator and the predicate NAI-5 Micromanipulator are motor-driven micromanipulators that allow the user to control the movement of a tool using the joystick on the Control unit. Motors in the Motor module unit shift the position of the tool in response to the joystick motions in X, Y, and Z directions. The manufacturers of both the proposed and predicate devices provide adapters for attaching the Motor module unit to inverted microscopes commonly used for assisted reproduction procedures. The proposed TransferMan® 4m Micromanipulator and predicate NAI-5 Micromanipulator are indicated for coarse and fine tool positioning.

The CellTram® Microinjectors and the predicate IM-11 Pneumatic Microinjector are used

to control aspiration of the sperm into the microcapillary, and after perforation of the oocyte to release of the sperm into the ooplasm. Both the proposed and predicate devices consist of manually controlled pistons that slide within a cylinder system in and out to aspirate or dispense. The CellTram® Air, the CellTram® Oil, and the CellTram® vario have different mediums used for pressure transmission (air versus oil). The predicate IM-11 Pneumatic Microinjector operates using air only.

The manufacturer believes that the technological characteristics of the TransferMan® 4m Micromanipulator and the CellTram® Microinjectors are substantially equivalent to those of the predicate devices.

The tables below provide the comparison of the characteristics between the proposed and predicated devices.

Side-by-Side Comparison of the TransferMan® 4m Micromanipulator with the NAI-5 Micromanipulator

	Feature	TransferMan® 4m Micromanipulator Eppendorf AG (Proposed)	NAI-5 Micromanipulator Set Narishige Col. Ltd System (K120877)
General	Intended Use	Intended for use in assisted reproduction procedures requiring coarse and fine positioning of a microtool under the microscope.	: "… enables course and fine positioning of a microtool under the microscope and is used in assisted reproduction procedures."
	Components	Motor Module Control Board	Drive Unit 2 Control Units for coarse and fine Power Supply
	Power Supply	Input: 120-240 V AC; 50-60 Hz	Input: 100-240 V; 50 Hz
	Range of movement	Coarse: 5 µm to 12,500 µm in 5 µm increments Fine: 5 µm to 2,000 µm in 5 µm increments X-Fine: 1 µm to 600 µm in 1 µm increments	Coarse: 22mm Fine: 10mm Increments not known
	Speed	0 - 10,000 µm/s	Max. 1.4 mm/s
Motor Module	Step Motors	X-,Y-,Z- Module	X-,Y-,Z- Module
	Step Size	< 20 nm (calculated resolution)	Not known
	Mechanical Adjustability	>80 mm	
	Dimensions	Module (X,Y,Z): 129 mm x 51 mm x 36 mm (W x D x H)	Drive Unit: 57 mm x 138 mm x 94 mm (W x D x H)
	Weight	Motor module (complete): 2.15 kg Module (X,Y,Z): 570g	Not known
	Maximum Traveling Distance	20 mm	Coarse: 22mm Fine: 10mm
	Swivel Joint Direction of Rotation	-45° – +90°	Not known

Feature		TransferMan® 4m Micromanipulator Eppendorf AG (Proposed)	NAI-5 Micromanipulator Set Narishige Col. Ltd System (K120877)
	Capillary Exchange	Direction of rotation: forward (swivel out)	
	Sample Replacement	Direction of rotation: backward (swivel in)	
	Operating Angle of Angle Head	0° – 90°	
	Microscope Compatibility	All major microscope brands: Leica, Nikon, Olympus, and Zeiss	All major microscope brands: Leica, Nikon, Olympus, and Zeiss
Control Unit	Dimensions	205 mm x 288 mm x 152 mm (W x D x H)	70 mm x 100 mm x 120 mm (W x D x H)
	Weight	Control board: 1.8 kg (includes mains/power supply device)	Not known
	Control Mechanism	Dual Speed joystick	Joystick
	Working range	Coarse, fine, x-fine	Coarse, fine
	Programmable	Yes	No
	External device/PC Connection	Serial interface SubD9, male	Not known
	Speed Control	Proportional and dynamic kinetics	

Side-by-Side Comparison of the CellTram® Microinjectors with the IM-11 Pneumatic Microinjector

Feature		CellTram® Microinjectors Eppendorf AG (Proposed)	IM-11 Pneumatic Microinjector Narishige Co., Ltd. (K113712)
General	Intended Use	Intended for use in Intra-Cytoplasmic Spermatozoa Injection (ICSI) procedures to aspirate and inject sperm into oocytes.	Intended for use for Intra-Cytoplasmic Sperm Injection (ICSI) procedures to aspirate and inject sperm into oocytes, and to hold oocytes during the ICSI procedure
	Microinjector Type	CellTram® Air (air transfer medium) CellTram® Oil (oil transfer medium) CellTram® vario (oil transfer medium, coarse/fine adjustment)	Air transfer medium
	Operation	Manual microinjection	Manual microinjection
	Minimum Adjustment Volume	<0.2 µL	Not known
	Adjustment total volume	2,640 µL	
Air	Applications	Gentle holding of larger cells, e.g. oocytes Manual microinjection, aspiration and dispensing of cells (e.g. sperms)	Holding oocytes Manual aspiration of sperm into injection pipette Microinjection of sperm into oocytes
	Type	Manual pressure	Manual pressure
	Pressure Generation	Piston/cylinder system, filled with air, maintenance-free	Pneumatic
	Max Pressure	2,900 hPa	Not known
	Minimum Setting Volume	<200 nL	Not known

Feature		CellTram® Microinjectors Eppendorf AG (Proposed)	IM-11 Pneumatic Microinjector Narishige Co., Ltd. (K113712)
	Total Setting Volume	2,640 µL	Not known
	Change in Volume (per dial revolution)	88 µL	coarse: 1.0 mL fine: 250 µL
	Max Range	15 mm (air)	40 mm (coarse and fine combined) 30 mm coarse 17 mm fine
Oil	Applications	Gentle holding of larger cells, e.g. oocytes Manual microinjection, aspiration and dispensing of cells (e.g. sperms)	Not Applicable
	Type	Manual hydraulic	
	Pressure Generation	Piston/cylinder system, filled with oil	
	Max Pressure	20,000 hPa	
	Minimum Setting Volume	<20 nL	
	Total Setting Volume	960 µL	
	Change in Volume (per dial revolution)	9.6 µL	
	Max Range	50 mm	
vario	Applications	Gentle holding of larger cells, e.g. oocytes Manual microinjection, aspiration and dispensing of cells (e.g. sperms) Manual aspiration, dispensing, and removal of cells and organelles (e.g. polar bodies).	Not Applicable
	Type	Manual hydraulic	
	Pressure Generation	Piston/cylinder system, with gear, filled with oil	
	Max Pressure	20,000 hPa	
	Minimum Setting Volume	<20 nL/<2 nL (coarse/fine)	
	Total Setting Volume	960 µL	
	Change in Volume (per dial revolution)	course: 9.6 µL fine: 0.96 µL	
	Max Range	50 mm	

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The safety and effectiveness of the proposed TransferMan® 4m Micromanipulator has been confirmed by hardware and software testing. The proposed micromanipulator complies with applicable requirements of the following standards:

- EN 61326- 1:2006, "Electrical Equipment for Measurement, Control and Laboratory

Use – EMC Requirements"

- EN 55011:2011, "Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Radio Disturbance Characteristics – Limits And Methods Of Measurement"
- EN 61000-4-2:2009-12, Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test
- EN 61000-4-3:2011-04, "Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test"
- EN 61000-4-4:2013-04, "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test"
- EN 61000-4-5:2007-06, "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 5: Surge immunity test"
- EN 61000-4-6:2009-12, "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 6: Immunity to conducted disturbances, induced by radio-frequency fields"
- EN 61000-4-11:2005-02, "Electromagnetic compatibility (EMC) – Part 4: Testing and measuring techniques – Section 11: Voltage dips, short interruptions and voltage variations immunity tests"
- UL 61010-1 Edition 2:2008/10/28, "Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements"

The safety and effectiveness of the proposed CellTram® Microinjectors has been confirmed by hardware testing. The proposed CellTram® Microinjectors underwent endurance testing. Packaging validation testing has been performed according to ASTM D4169-09, "Standard Practice for Performance Testing of Shipping Containers and Systems".

8. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The indications for use, principles of operation, and technological characteristics of the TransferMan® 4m Micromanipulator and CellTram® Microinjectors are substantially equivalent to the predicate devices NAI-5 Micromanipulator (subject of K120877) and IM-11 Pneumatic Microinjector (subject of K113712), respectively. Differences between the proposed devices and the predicate devices are limited to minor differences in technological characteristics. These differences do not impact the safety and effectiveness of the micromanipulator or microinjectors for their intended use.

The safety and performance of the TransferMan® 4m Micromanipulator and CellTram® Microinjectors for their intended use is demonstrated by non-clinical testing. Based on the evidence provided, Eppendorf believes that the proposed TransferMan® 4m Micromanipulator and CellTram® Microinjectors are substantially equivalent to the predicate devices NAI-5 Micromanipulator and IM-11 Pneumatic Microinjector and the differences between the products are minor, and raise no new issues of safety and effectiveness.